

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1015 (GBW)
	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	
	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant and Counter-Plaintiff	)	
	)	
v.	)	
	)	
NIPPON SHINYAKU CO., LTD. and	)	
NS PHARMA, INC., Plaintiff and Counter-	)	
Defendants.	)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM NIPPON  
SHINYAKU CO. AND NS PHARMA, INC. REGARDING REQUEST FOR LEAVE  
TO FILE AN AMENDED ANSWER TO SAREPTA'S COUNTERCLAIMS**

Amanda S. Williamson (admitted *pro hac vice*)  
Christopher J. Betti (admitted *pro hac vice*)  
Krista V. Venegas (admitted *pro hac vice*)  
Wan-Shon Lo (admitted *pro hac vice*)  
Maria E. Doukas (admitted *pro hac vice*)  
Zachary Miller (admitted *pro hac vice*)  
Guylaine Haché (admitted *pro hac vice*)  
Michael T. Sikora (admitted *pro hac vice*)  
110 N. Wacker Drive, Ste 2800  
Chicago, IL 60601  
Telephone: 312.324.1000  
Fax: 312.324.1001  
amanda.williamson@morganlewis.com  
christopher.betti@morganlewis.com  
krista.venegas@morganlewis.com  
shon.lo@morganlewis.com  
maria.doukas@morganlewis.com  
zachary.miller@morganlewis.com  
guylaine.hache@morganlewis.com  
michael.sikora@morganlewis.com

Amy M. Dudash (DE Bar No. 5741)  
Morgan, Lewis & Bockius LLP  
1201 N. Market Street, Suite 2201  
Wilmington, DE 19801  
Telephone: 302.574.3000  
Fax: 302.574.3001  
amy.dudash@morganlewis.com

*Attorneys for Plaintiff/Counterclaim Defendant  
Nippon Shinyaku Co., Ltd. and Counterclaim  
Defendant NS Pharma, Inc.*

Dated: March 23, 2023

Eric Kraeutler (admitted *pro hac vice*)  
1701 Market Street  
Philadelphia, PA 19103  
Telephone: 215.693.5000  
Fax: 215.963.5001  
eric.kraeutler@morganlewis.com

Dear Judge Williams:

Pursuant to Federal Rule of Civil Procedure 15(a)(2), Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) respectfully move the Court for leave to file an Amended Answer to Sarepta’s Counterclaims and New Counterclaims (attached as Ex. 1). The parties met and conferred on March 22, 2023, and Sarepta Therapeutics, Inc. (“Sarepta”) opposes NS’s motion.

### **Background**

On December 12, 2022, the Court entered a Scheduling Order, which set a deadline to amend or supplement the pleadings of March 23, 2023. D.I. 143 ¶ 2. The deadline for substantial document production was January 20, 2023, and fact discovery closes on July 27, 2023. *Id.* ¶ 4.

NS seeks to add counterclaims of inequitable conduct and *Walker Process* fraud based on Sarepta’s assertion of United States Patent Nos. 9,994,851, 10,227,590, and 10,266,827 (collectively, the “UWA Patents”) against Nippon Shinyaku. *See* Am. Answer Countercl., D.I. 89. The inequitable conduct counterclaim is based on a knowingly false claim of priority.

The UWA Patents claim priority to a common PCT Application, PCT/AU2005/000943 (the “PCT Application”) filed on June 28, 2005. The UWA Patents each claim a genus of morpholino antisense oligomers (ASOs) that encompasses a vast number of ASOs. [REDACTED]

[REDACTED] In the UWA Patent specification and during prosecution, [REDACTED] acknowledged the unpredictability of identifying ASOs that are capable of inducing exon skipping. *E.g.*, ’851 Patent, 3:43-44, 4:19-22, 32:15-21; 2018-01-05 Amendment, at 10. The [REDACTED] and numerous admissions of unpredictability demonstrate that, as of the PCT filing date, [REDACTED] **did not know** and **could not have predicted** whether *any* ASOs structurally within the claimed genus would “induce[] exon 53 skipping,” as also required by the claims. Thus, [REDACTED] had not in fact invented the claimed genus.

Notwithstanding their knowledge that they had neither created, appreciated, recognized, described nor enabled the claimed genus of ASOs, [REDACTED] along with their attorneys, and yet-to-be-determined individuals at the University of Western Australia (“UWA”) and Sarepta involved in the prosecution of the UWA Patents, knowingly submitted false claims of priority to the PCT Application. The reason for this material misrepresentation is clear: these individuals wanted to avoid the numerous references published after the claimed priority date that would have been material to patentability had the USPTO considered them as prior art. The single most reasonable inference drawn from the evidence is that [REDACTED] and the Attorneys intended to deceive the USPTO by intentionally and falsely claiming priority to the PCT Application. Thus, the UWA Patents were procured by fraud on the USPTO. And by asserting the fraudulently procured UWA Patents against its sole competitor in the market, Sarepta (and proposed counter-plaintiff UWA) have committed *Walker Process* antitrust violations.

### **Leave to Amend Should be Freely Granted**

Leave to amend “should be granted freely.” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486 (3d Cir. 1990). Such amendments “enable a party to assert matters that were . . . unknown at the time the party interposed the original complaint.” *Garrett v. Wexford Health*, 938 F.3d 69, 82 (3d Cir. 2019). Leave should be granted absent a showing of “undue delay, bad faith or dilatory motives” or where the amendment would be futile or prejudice another party. *WiTricity Corp. v.*

*Momentum Dynamics Corp.*, 563 F. Supp. 3d 309, 326 (D. Del. 2021). None of these factors are present here, and, thus, the Court should grant NS leave to amend its Answer.

***There Is No Undue Delay, Bad Faith, or Undue Prejudice to Sarepta***

NS's motion for leave is filed within the deadline for filing an amended pleading set in the Scheduling Order of March 23, 2023—a deadline agreed upon by the parties. Accordingly, this strongly supports the conclusion that the amendment is timely and not filed with bad faith or a dilatory motive, and would not unduly prejudice Sarepta. *Invensas Corp. v. Renesas Elecs. Corp.*, No. 11-448-GMS-CBJ, 2013 WL 1776112, at \*3 (D. Del. Apr. 24, 2013). Moreover, NS diligently worked to amend its Answer after learning of facts supporting its additional claims.

Inequitable conduct and *Walker Process* claims often require “critical evidence” which “can be obtained only from the patentee” and therefore it is common that these claims “arise only after discovery has been conducted.” *Lipocine Inc. v. Clarus Therapeutics, Inc.*, No. 19-622 (WCB), 2020 WL 4794576, at \*3 (D. Del. Aug. 18, 2020). Counsel for NS learned of the facts showing Sarepta's lack of conception and reduction to practice by reviewing documents that Sarepta produced on December 1, 2022, January 4, 2023, and January 20, 2023. Upon reviewing those documents, counsel for NS worked diligently to draft an Amended Answer. Thus, there is no undue delay, bad faith, or dilatory motive. *Invensas*, 2013 WL 1776112, at \*3.

Sarepta will not be unduly prejudiced if the Court grants NS leave to amend its Answer. The inequitable conduct and *Walker Process* fraud claims can be integrated into the case without impacting the trial date. The parties are still in fact discovery and no depositions have been taken. Moreover, the discovery required for the additional claims and pending claims are substantially commensurate, reducing any perceived prejudice to Sarepta. *See Micron Tech., Inc. v. Rambus Inc.*, 409 F. Supp. 2d 552, 559 (D. Del. 2006).

***NS's Amended Answer Is Not Futile***

The new counterclaims in NS's proposed Amended Answer are not futile. An amendment is futile only if it does not fulfill “the standard of legal sufficiency” of Federal Rule of Civil Procedure 12(b)(6). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).

**NS's Inequitable Conduct Claim Is Not Futile**

Inequitable conduct is pled with sufficient particularity if it includes allegations that “identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1331 (Fed. Cir. 2009). NS alleges that [REDACTED] UWA, licensee Sarepta [REDACTED] and their attorneys submitted a false claim of priority to the USPTO. Ex. A ¶¶ 27-30, 41-45, 76-79; *see Exergen*, 575 F.3d at 1329 (The duty of candor applies to individuals.). A priority claim is inherently material to patentability. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1233 (Fed. Cir. 2007). Further, NS alleges that [REDACTED] and their attorneys were aware of certain references published after the claimed priority date that each disclosed species within the claimed genus and therefore would have been but-for material to patentability had the USPTO considered them as prior art. Ex. A ¶¶ 80-87; *see Exergen*, 575 F.3d at 1329 (pleading must include facts identifying particular teachings in withheld reference and specific limitations in claims to which those teachings are relevant).

Finally, NS alleges that the single most reasonable inference able to be drawn from the evidence is that [REDACTED] and their attorneys intended to deceive the USPTO by intentionally and falsely claiming priority to the PCT Application. Accordingly, NS's inequitable conduct claim is

not futile. *See Baxalta Inc. v. Bayer Healthcare LLC*, No. 17-1316-RGA-SRF, 2021 WL 7441631, at \*6-7 (D. Del. Aug. 22, 2021) (“[I]t is reasonable to infer that an applicant who is aware of material prior art and the possible adverse effect that disclosure could have on the application would have an incentive to conceal the prior art.”).

NS’s Walker Process Fraud Claim Is Not Futile

“[M]aintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under § 2 of the Sherman Act.” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 173 (1965). As explained above, NS’s proposed Amended Answer sufficiently pleads a claim for inequitable conduct. *See TransWeb, LLC v. 3M Innovative Prods. Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016) (*Walker Process* claims require showing of inequitable conduct). NS has also sufficiently pled facts demonstrating that Sarepta has “engaged in predatory or anticompetitive conduct with [] a specific intent to monopolize.” *See id.* (“[T]he showing required for proving inequitable conduct and the showing required for proving the fraud component of Walker Process liability may be nearly identical.”).

NS’s Amended Answer also sufficiently pleads that there is “a dangerous probability of achieving monopoly power.” *Id.* at 1306 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)). NS alleges that the relevant product market is DMD patients with mutations amenable to exon 53 skipping who have been prescribed with an antisense oligomer therapy and that [REDACTED] Ex. A ¶¶ 97, 102; *Targus Int’l LLC v. Victorinox Swiss Army, Inc.*, No. 20-464-RGA, 2020 WL 7264199, at \*6, \*8 n.12 (D. Del. Dec. 10, 2020) (The pleadings must include allegations of the “relevant market” but need not allege the “precise percentage of market share the defendant holds.”). There are no reasonable substitutes because unlike NS’s and Sarepta’s ASO therapies, “other FDA-approved therapies for DMD, such as corticosteroids, are mainly prescribed for symptom management and do not restore dystrophin levels.” Ex. A ¶¶ 101-102.

Moreover, NS has pled facts showing that it has suffered, and will continue to suffer an antitrust injury, including forcing NS “to expend substantial amounts of money, time, and human resources in order to defend against the claims.” Ex. A ¶¶ 105-107; *TransWeb*, 812 F.3d at 1312 (“abuse of the legal process” makes “attorney fees incurred by the antitrust-plaintiff during that legal process a relevant antitrust injury”). Sarepta’s anticompetitive infringement claims require NS to cease competition, take a license, or defend the infringement claims—regardless of the option NS elects, NS in a disadvantageous competitive position. These facts demonstrate that Sarepta has a “dangerous probability of achieving monopoly power.” *Targus*, 2020 WL 7264199 at \*8 (the dangerous probability factor “implicates a ‘particularly fact-intensive inquiry’” which is rarely appropriate to resolve at pleading stage) (quoting *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007)).

\*\*\*

NS seeks leave to file an Amended Answer to Sarepta’s Counterclaims within the jointly proposed deadline for amending pleadings set by the Scheduling Order. NS has diligently worked to amend its Answer after learning of the facts supporting its claims. NS therefore respectfully requests the Court grant its Motion for leave to file an Amended Answer.

March 23, 2023

Amanda S. Williamson (admitted *pro hac vice*)  
Christopher J. Betti (admitted *pro hac vice*)  
Krista V. Venegas (admitted *pro hac vice*)  
Wan-Shon Lo (admitted *pro hac vice*)  
Maria E. Doukas (admitted *pro hac vice*)  
Zachary Miller (admitted *pro hac vice*)  
Guylaine Haché (admitted *pro hac vice*)  
Michael T. Sikora (admitted *pro hac vice*)  
110 N. Wacker Drive, Ste 2800  
Chicago, IL 60601  
Telephone: 312.324.1000  
Fax: 312.324.1001  
amanda.williamson@morganlewis.com  
christopher.betti@morganlewis.com  
krista.venegas@morganlewis.com  
shon.lo@morganlewis.com  
maria.doukas@morganlewis.com  
zachary.miller@morganlewis.com  
guylaine.hache@morganlewis.com  
michael.sikora@morganlewis.com

Eric Kraeutler (admitted *pro hac vice*)  
1701 Market Street  
Philadelphia, PA 19103  
Telephone: 215.693.5000  
Fax: 215.963.5001  
eric.kraeutler@morganlewis.com

Respectfully submitted,

/s/Amy M. Dudash  
Amy M. Dudash (DE Bar No. 5741)  
1201 N. Market Street, Suite 2201  
Wilmington, Delaware 19801  
Telephone: 302.574.3000  
Fax: 302.574.3001  
amy.dudash@morganlewis.com

*Attorneys for Plaintiff/Counterclaim  
Defendant Nippon Shinyaku Co., Ltd. and  
Counterclaim Defendant NS Pharma, Inc.*